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Do-It-Yourself Medical Testing

by Dixie Farley

Ralph Waldo Emerson had his finger on the pulse of the American spirit in his 1841 essay *Self-Reliance*. "Trust thyself," he wrote. "Every heart vibrates to that iron string."

True then, true today. We Americans value the independence of taking charge of our own lives. But when it comes to monitoring one's own pulse and performing other medical self-tests, an independent spirit can be both a boon and a bane.

To manufacturers of home medical tests, consumers' reliance on their products is indeed a financial boon—roughly $667.7 million in sales in 1986. And that market should reach $2.2 billion by 1995, according to FIND/SVP, a New York market research firm. To consumers, the self-reliant surge in health care often means lower medical costs, a closer watch on chronic conditions, and earlier detection of health problems.

Where's the bane? It's the risk of misinterpreting or overrelying on test results so that a single abnormal reading is taken as a "diagnosis" of illness or disease, or a return to normal readings is taken as a "cure." In other words, it can be dangerous to go overboard in making medical decisions without professional medical advice.

Still, medically trained or not, people are testing their eyesight, stool, urine, blood, and blood pressure in search of health clues related to vision problems, gastrointestinal diseases, infection, ovulation, pregnancy, diabetes, hypertension, and other conditions.

Several things seem to be promoting the self-testing surge, not the least of which is the fact that the tests are relatively inexpensive and simple, yet fairly reliable. Screening programs to reduce the impact of disease through early detection point up the national trend toward preventive medicine. People are living longer, so the need to monitor diabetes, high blood pressure, and other chronic health problems is increasing. About 80 percent of the elderly are indeed said to have at least one chronic condition. And, with medical expenses three times what they were 10 years ago, people are looking for ways to save money.

In general, there are three categories of self-testing products: (1) those that help diagnose a specific condition or disease in people with symptoms—such as using a pregnancy test kit after a missed period;
(2) screening tests that identify indications of disease in people without symptoms—as in examining stool for hidden blood; and (3) doctor-recommended monitoring devices that provide ongoing checkups on an existing disease or condition—blood glucose testing by diabetics, for instance. Many of these tests analyze urine, blood, or other fluid or tissue samples taken from the body. Such tests are called *in vitro* (outside the body) diagnostics.

Self-tests can offer many health benefits. A woman being treated for infertility problems can pinpoint her time of ovulation. A more accurate picture of blood pressure fluctuation is beneficial information for both doctor and patient. And thanks to convenient portable tests, patients with chronic health problems can maintain testing regimens away from home. An example is glucose monitoring, which has long helped diabetics keep their disease under control so they can live healthier, more normal lives. Further, fecal occult (hidden) blood test kits are believed to have such potential for detecting early indications of colorectal cancer that the American Cancer Society has been distributing free kits. The society says that early detection and prompt treatment could save the lives of three out of four patients with that type of cancer and recommends, therefore, that people over 50 have their stool tested every year.

Many health professionals believe that properly administered self-tests show great promise for improving the public health, *provided* the tests are performed in conjunction with medical guidance. It's when testing is done without such guidance that the self-reliant American spirit causes problems.

To illustrate: Lay users might translate "self-test" as "self-diagnosis." But considering the results of one test to be a diagnosis is risky. The user may perform the test incorrectly, causing hidden blood to go undetected. And, a positive test result doesn't always signify colon or rectal cancer. It also can reflect such factors as bleeding gums or last night's T-bone steak. The fact is, a diagnosis by a physician involves an evaluation of the patient's medical history, a physical examination, most likely other tests, and sometimes consultation with other medical experts. And even a carefully gathered patient profile is subject to error.

That's not to say self-tests are unreliable. When used as directed, they're considered safe and effective. The Food and Drug Administration's Center for Devices and Radiological Health, which regulates medical devices, requires that devices used by a lay person comply with the same regulations to ensure safety and effectiveness as devices used in professional laboratories. A self-test, however, presents variables not present in its professional counterpart.

First, professional laboratories are designed and managed specifically for scientific testing. Proper lighting, chemical storage requirements, instrument maintenance, sanitary conditions, and supervisory review of results provide a measure of reliability and uniformity to test results. Technicians have training, experience and expertise in conducting the tests—some states even require that technicians be licensed. In comparison, a first-time user conducting a test at home bypasses those factors and the level of accuracy they promote.

The inexperienced, untrained user may misinterpret results, a mistake that can be compounded by the fact that no test is 100 percent accurate even under the best conditions and that results can differ from brand to brand. A case in point is a pregnancy test. When a urine sample contains enough of a certain hormone, a signal should occur to indicate a possible pregnancy. But the kits are made by several firms, so the hormonal level that triggers the signal may vary according to the design of each manufacturer. Moreover, all pregnant women don't produce the hormone at the same rate, so a woman could be pregnant but not yet be producing enough hormone to prompt the signal from the particular test she's using. Thus, a test could produce a "false negative." That is, it might indicate no pregnancy when, in fact, conception had occurred. If the woman continued certain practices, such as smoking or taking potentially harmful drugs, she would be risking her baby's health.

Several popular books and articles have described a number of self-testing products that are unavailable over-the-counter at drugstores but can be bought from medical supply firms without a prescription. Many of those products, though, are intended for use by medically trained professionals or for lay use only under a

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physician's guidance. For example, an ophthalmologist (a physician who specializes in eye diseases) might show a patient with glaucoma how to use a tonometer to self-monitor pressure inside the eye. This test also would require prescription anesthetic eyedrops for the patient. Consumers should be aware that FDA has *not* determined whether the directions for using products intended for purchase by medical professionals are adequate for patient interpretation. The potential for error in a lay person's conducting those tests and interpreting the results is unknown.

Some health professionals are concerned about the value of self-testing for a condition when there's already a symptom, as in testing for pregnancy when a menstrual period is overdue. In other words, regardless of the reason for a missed period, the symptom calls for medical advice.

On the other hand, a positive result with a home pregnancy test may spur a woman to seek medical care early in her first trimester. According to Tom Tsakeris, of FDA's Center for Devices and Radiological Health, "If people are concerned enough to spend $10 or so on a test, one might assume that they'd be concerned enough to follow up and go to the doctor."

Tsakeris says the overall value of self-testing is tied to teaming patient with physician for better medical care. "Clearly," he says, "there's potential for improved treatment when the physician can say, 'Here's your condition. I want you to go home and test yourself periodically with this test and report the results back to me.' And when the results of an off-the-shelf test prompt someone to get needed medical care earlier than would have occurred without the test, that's a significant benefit, too."

As for the future, what new benefits might this trend in self-testing garner? Writing in *Clinical Chemistry* (June 1984), Alfred and Helen Free of Ames Division of Miles Laboratories, a major manufacturer of medical testing kits, forecast many possibilities: Newborns in remote areas might be tested for inborn errors of metabolism; patients might take certain tests before medical appointments; parents could test children as part of each child's permanent health record; and members of retirement communities could monitor their health. The Frees predict new self-tests for cholesterol, syphilis, herpes, enzymes, drug monitoring, and diet monitoring for vitamins, minerals, protein, and overall nutritional status.

To promote self-testing safety and effectiveness, here are some general precautions (all precautions do not necessarily apply to all tests):

- For test kits that contain chemicals, note the expiration date. Beyond that date, chemicals may lose potency and affect results. Don't buy or use a test kit if the date is past.
- Consider whether the product needs protection from heat or cold. If so, don't leave it in the car trunk or by a sunny window on the trip home. At home, follow storage directions.
- Study the package insert. First read it through to get a general idea of what the test is about. Then go back and study the instructions and pictures until you fully understand each step.
- If something isn't clear, don't guess. Consult a pharmacist or other health professional. Or check the insert for a toll-free "800" number to call.
- Learn what the test is *intended* to do and what its limitations are. Remember: The tests are not 100 percent accurate.
- If color is a part of the test and you're colorblind, be sure someone who *can* discern color interprets the results.
- Note special precautions, such as avoiding physical activity or certain foods and drugs before testing.
- Follow instructions exactly, including the specimen collection process if that is a part of the test. Sequence is important. Don't skip a step. If a step to validate the test or calibrate an instrument is included, do it.
- When collecting a urine specimen—unless you use a container from a kit—wash the container thoroughly and rinse out all soap traces, preferably with distilled water, which is generally purer than tap or other bottled water.
- When a step is timed, be precise. Use a stopwatch or at least a watch with a second hand.
- Note what you should do if the results are positive, negative, or unclear.
- Keep accurate records of results.
- As with medications, keep test kits that contain chemicals out of the reach of children. Promptly discard used test materials as directed.

For details about some individual tests, see the accompanying chart.

Any malfunction of a self-test should be reported to the manufacturer or to FDA through the agency's reporting system at the U.S. Pharmacopeia. To report a problem to the pharmacopeia, write to: USP, Problem Reporting Program, 12601 Twinbrook Parkway, Rockville, Md. 20852, Attn: Dr. Joseph G. Valentino. Another reporting option, especially in an emergency, is to call the nearest FDA district office listed in the telephone directory. Describe the product completely, stating the product name, type, and—as appropriate—serial and lot numbers, dosage strength, and expiration date. Explain all details of the problem, including the date it occurred. ■

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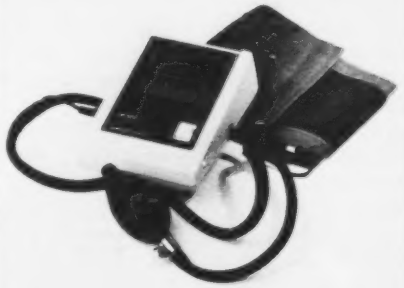
meat; certain raw fruits and vegetables, such as melons, turnips, broccoli, cauliflower, red radishes or horseradish; and drugs such as aspirin, indomethacin, corticosteroids, reserpine, or phenylbutazone. False negative results may be caused by high intake of vitamin C (over 250 milligrams a day) or laxatives with mineral oil. Despite repeated negative results, consult a physician promptly if you have other symptoms—for example, unexplained weight loss or any change in bowel habits (such as diarrhea or constipation) lasting longer than two weeks.



BLOOD PRESSURE

Function

Measures blood pressure, which is the pressure of blood on the walls of the arteries. The measurement consists of two numbers: The first (the higher number) is the systolic blood pressure—when the heart is in contraction. The second is the diastolic pressure—when the heart is in relaxation. (See "The Story Behind Those High Blood Pressure Readings" in the May 1981 *FDA Consumer.*)

How It Works

Most kits include a cuff (air bladder), a monitoring device (sphygmomanometer), and a listening device (stethoscope or microphone). The center of the cuff—or the microphone—is placed directly on the pulse point of the artery in the upper arm. The cuff is wrapped around the arm just above the elbow and is inflated rapidly until it stops the blood flow. With a stethoscope, the user—or the instrument, if a microphone is used—listens for sounds in the artery to detect systolic and diastolic blood pressures and records the readings. Instructions vary with the instrument's degree of automation. Blood pressure is usually lower in the morning and increases from the afternoon on, so test daily at about the same time. The standard-size cuff fits arms up to 13 inches in diameter. People with larger arms should order a larger cuff. The newer finger-cuff blood pressure monitors are as effective as arm-cuff devices, unless a person has poor blood circulation to the hands. The finger should be slipped all the way into the cuff but kept level with the heart; in other words, the user should sit rather than lie down and should not hold the device higher or lower than the heart. Follow the manufacturer's instructions carefully.

Time for Results

2 to 5 minutes

Comments

In people 18 to 45, normal systolic pressure is about 120 millimeters of mercury (mm Hg); normal diastolic pressure is near 80 mm Hg. That's generally expressed as 120 over 80. In older people, somewhat higher pressures are normal. If repeated readings show that systolic pressure is over 140 and diastolic pressure is over 90, consult a physician promptly. The body should be at normal temperature, neither too hot nor too cold. A room colder than 60 degrees Fahrenheit, for instance, is too cold for taking a blood pressure reading. This is especially true for finger cuff monitors; cold fingers may give low readings or no reading at all. Inaccurate readings can be caused by extraneous noises affecting the listening device, anxiety, movement during measurement, or an incorrectly placed or incorrectly deflated (too fast, too slow) cuff. Eating, drinking, smoking, or exercising before testing can also affect results. An average of three readings, 5 to 10 minutes apart is more accurate than a single reading. The device should be checked for accuracy against a physician's blood pressure monitor. Regardless of results, people should never stop or change medication for high blood pressure without consulting a physician.

(Courtesy Dacomed Corporation)

IMPOTENCE

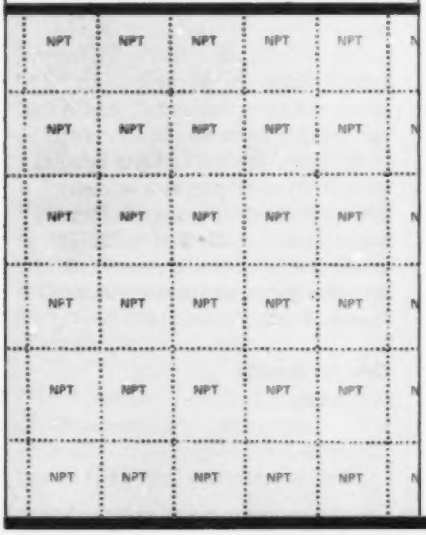
Function

Detects and measures the rigidity of erections of the penis during sleep. The test is intended for use by men who appear unable to have an erection for sexual intercourse.

How It Works

A soft fabric band is placed around the penis before the man goes to bed at night. Attached to the device are three small plastic strips that are designed to break at different degrees of force. The test is based on the principle that adult males have two to five erections during sleep. (Another test is available that consists of stamps placed around the penis. If the stamps break, this indicates that an erection has occurred during sleep but not whether erections occurred repeatedly nor whether they sustained rigidity.)

(Photo courtesy of Oregon Health Sciences University)



Time for Results

Overnight

Comments

If all three strips break, the cause of the impotence most likely is psychological. If the strips don't break, the cause is probably physical. There are treatments for both types of impotence. (See "New Treatments for Impotence," in the December 1985-January 1986 *FDA Consumer.*)

VISION

Function

Screens for visual acuity problems, macular degeneration, and glaucoma.

How It Works

- Tests 1 and 2—Visual acuity. (1) A four-line eye chart is read alternately with each eye, while a small card is held over the eye not being tested. If the user can read the 20/40 line with each eye, test 2 is omitted. (2) The same chart is read again, but this time the letters are sighted through a cluster of pinholes in a card held over the eye being tested. If the user can read the 20/40 line with each eye, corrective lenses or a prescription change may be all that's needed. If the user cannot read the 20/40 line, there may be a more serious problem and the user should consult an ophthalmologist (a physician who specializes in eye diseases) right away.
- Test 3–Macular degeneration. This test uses the "Amsler Grid," a square card divided into smaller squares of equal size. With both eyes open, the user looks at a black dot in the center of the grid; each eye is alternately covered. If squares around the dot are distorted (bending of the straight lines) or disappear when one eye is covered, this may indicate macular degeneration, a condition that destroys part of the retina, and an ophthalmologist should be consulted promptly.
- Test 4—Glaucoma survey. Five questions are asked. If any are answered "yes" and if the pressure within the eye hasn't been tested for glaucoma in the last 2 years, visit an eye specialist to have the test.

Time for Results

2 to 3 minutes (four tests)

Comments

Even if all tests are "passed," eye health is not guaranteed. If there are vision problems, eye pain, redness or discharge, seek a professional eye exam.

A Consumer's Guide to Home Medical Tests

BLOOD GLUCOSE MONITORING

Function
Measures the level of glucose (a type of sugar) in blood. The tests are *not* intended to diagnose diabetes. Glucose self-monitoring should be done under a physician's guidance. Glucose concentration in blood indicates the body's ability to metabolize carbohydrates. Because diabetics can't use carbohydrates normally, they monitor their glucose levels so they can adjust diet or medication to normalize their carbohydrate processing. (For more information about glucose self-monitoring, contact a local chapter of the American Diabetes Association or the Juvenile Diabetes Foundation. See also "Diabetes Is a Controllable Disease with a Growth Factor," in the November 1982 *FDA Consumer.*)

How It Works
After a thorough handwashing, the user pricks a finger or earlobe to obtain a drop of blood. The specimen is placed on a chemically treated test strip, where the chemical reacts with glucose in the blood to produce a color. After a specified time (this varies from brand to brand), the blood is blotted or wiped off the strip. After another time period, the color on the strip is matched to a color guide. Color intensity varies according to the specimen's glucose concentration. Test strips are also available for use with an electronic monitor, which times the steps automatically and displays the blood glucose value numerically. Skill in testing should increase with practice. Urine glucose tests are also available, but they're not as accurate as blood tests.

Time for Results
1 to 2 minutes

Comments
If results seem inconsistent with other symptoms, test again and, if results still seem questionable, consult a physician.

OVULATION MONITORING

Function
Measures the amount of luteinizing hormone (LH) in urine. A woman's body produces LH throughout the menstrual cycle, but at mid-cycle that production suddenly increases. Called the LH surge, the sudden hormone increase triggers ovulation, or the release of an egg from the ovary. Usually, ovulation occurs 24 to 36 hours after the LH surge begins. This test is *not* intended for use in contraception.

(Photo courtesy of Quidel)

How It Works
Once a day for about a week in the middle of the menstrual cycle, a chemically treated strip is dipped in a urine specimen. Comparing the strip with a color guide should indicate when an LH surge begins. In diluted urine, the test may not detect the hormone. So keep liquid intake fairly constant, urinate every 3 hours or so, and avoid excess liquid intake just before collecting the urine.

Time for Results
20 minutes to 1 hour

Comments
If an LH surge of more than 4 days in a row is indicated, consult a physician promptly. This could be caused by such conditions as pregnancy, ovarian failure, early menopause, endometriosis, or response to a medication.

PREGNANCY

Function
Detects human chorionic gonadotropin (hCG) hormone in urine. The hCG hormone is produced by a developing placenta.

How It Works
In a small test tube, chemicals are mixed with a urine specimen. A positive result is signaled (this varies from brand to brand) by the presence or absence of a ring formation, seen by the user looking down into the tube, or by a color change in the solution or on a dipstick. Because all pregnant women don't produce the hormone at the same rate, a positive result is more likely if testing is delayed until at least 7 to 9 days after the missed period should have occurred.

Time for Results
20 minutes to 2 hours

Comments
If the test results are positive, consult a physician promptly. If the results are negative, you still could be pregnant, so test again in a week. If a second negative result occurs but you're not yet menstruating, consult a physician promptly. When there's a pregnancy outside the uterus—in a Fallopian tube, for instance—the hCG hormone level remains low and may not trigger the test's signal. Meanwhile, without medical treatment, you may be at risk of hemorrhaging. False results may be caused by such factors as infection, an ovarian cyst, excess urinary protein, or certain medications. Placing the test on a vibrating surface, such as a refrigerator, or allowing it to incubate or reach its end point in sunlight could produce a false result.

URINARY TRACT INFECTIONS

Function
Detects *nitrite* in urine. Urine normally contains small amounts of *nitrate*. The bacteria that cause nearly all urinary tract infections change nitrate in urine to nitrite.

How It Works
On three consecutive mornings, a chemically treated test strip is dipped in a urine specimen. If nitrites are detected, there will be a uniform color change on the strip—not just color in spots or around the edge. (Another dipstick test identifies urinary tract infections by detecting white blood cells in urine.)

Time for Results
30 to 40 seconds

Comments
If results are positive, consult a physician promptly. But since 1 in 10 infections may be caused by bacteria that won't react with the test's reagent, a false negative can occur. So if results are negative but other symptoms—such as frequent, painful urination or pus-like discharge—are present, consult a physician promptly.

HIDDEN FECAL BLOOD

Function
Detects hidden (occult) blood in stools. This test is intended to screen people without symptoms. It does *not* replace a regular checkup by a physician. Someone who has already observed blood in stools should consult a physician.

How It Works
A stool specimen is brought into contact with peroxide and guaiac, a chemical sensitive to blood. (The specimen-collecting process varies from brand to brand.) If hidden blood is present, a color change will appear. Since bleeding may be intermittent, the American Cancer Society recommends taking specimens from three separate bowel movements. There are diet restrictions that should be followed before testing, but a special diet or a prescription drug regimen shouldn't be changed without consulting a physician. Toilet deodorizers and cleaners could affect results in some tests, so follow any instructions about removing them. Don't use rectal ointments just before or during the testing time. Don't test if you're already bleeding, as from hemorrhoids, menstruation, or cuts on the hand.

Time for Results
30 seconds to 16 minutes

Comments
Blood may appear in the stools from such causes as bleeding gums, hemorrhoids, ulcers, diverticulitis, colitis, polyps, or colon or rectal cancer. If results are positive, consult a physician promptly—the earlier a gastrointestinal problem is detected, the easier it is to treat. False positive results may be caused by many factors, including the intake of dietary iron supplements; red

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